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| EXAMINER | |
|---|---|
| MEHTA, BHISMA | |

| ART UNIT | PAPER NUMBER |
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| 3767 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/687,517 | HOMMANN ET AL. | |
| | Examiner | Art Unit | |
| | BHISMA MEHTA | 3767 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *15 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-6,8,9,12,13,17 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,9,12,13,17 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Specification*

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to disclose the one-piece lever forming an integral lever and protrusion and the needle protector comprising a sleeve in abutting contact with one of the holder for the product container or the product container.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacklich (U.S. Patent No. 4,444,560). Jacklich discloses an injection device for administering a fluid product having a casing (9), a piston rod (61) for dispensing the fluid product from a product container (37), and operating means for operating the piston rod. The operating means are provided laterally on a circumferential surface of the casing and

are formed as a one-piece lever (65) comprising an integral lever arm and protrusion (at 65). The protrusion projects from the lever arm at a fixed angle substantially perpendicular to the lever arm towards a longitudinal axis of the injection device as seen in Figure 1 towards a longitudinal axis of the injection device and extends into the casing. The operating means is pivotable in a radial direction relative to the casing about a fulcrum (shown at 51) and the protrusion is co-operable with an end of the piston rod opposite a piston via a surface oblique relative to a longitudinal axis of the casing (Figure 1). Figure 1 shows the protrusion being co-operable with the distal end of the piston rod (61). The proximal end of the piston rod is shown at 69 in Figure 1. Jacklich discloses that pivoting the lever arm of the operating means causes the protrusion to move along the oblique surface and displaces the piston rod. As seen in Figure 1, the fulcrum is provided on the circumferential surface in a generally central area of the injection device. The oblique surface is provided on the piston rod or can also be considered to be provided on the protrusion. At least a portion of the protrusion is connected to the piston rod by a T-connection such that the protrusion and the piston rod can slide relatively. As to claim 5, Jacklich discloses an indicator for indicating a product amount in the product container in the form of the ratchet teeth which are operated by pivoting the operating means (lines 40-44 of column 2).

4. Claims 6, 9, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Brunel (U.S. Patent No. 6,575,939). Brunel discloses an injection device having a casing (10), dispensing means (6) for dispensing a fluid product from a product container (1) containing an amount of the fluid product, and operating means (7). The

injection device also includes a dosing means with a releasing element (15) which projects radially outward and extends through an opening in the casing and an indicator for indicating a product amount remaining in the container where the ring being positioned as shown in Figure 11 would indicate that there is no product remaining in the container (1) (i.e., the product amount remaining in the container is zero) (lines 11-14 of column 9). As seen in Figure 2, 8, 9, 11-13, and 16, the releasing element (15) is shown to project radially outward from inside the casing and extend through the opening (shown at 17 in Figure 2, also see lines 1-16 of column 6). Specifically, in Figures 2, 8, 9, 11-13, and 16, the releasing element is shown projecting radially outward from inside the casing, while in Figure 10, the releasing element is within the casing. The releasing element is moved from a first stopper on a first side of the opening to a second stopper on a second side of the opening which is opposite to the first side as seen in Figures 14 and 15. The dimensions of the opening limit the movement of the releasing element, thereby setting the predetermined amount of the dosage and the indicator counts down by a dosage unit when the releasing element is moved (lines 34-39 of column 5 and lines 11-14 of column 9). As to claim 12, a guiding means (26) is provided which is capable of guiding a needle cap to exchange the injection needle of the device.

5. Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Bergens et al (U.S. Patent No. 6,270,479). Bergens et al disclose an injection device having a casing (111), a product container for fluid product (121), a holder (130) for the product container, an injection needle (123), a needle cap (127), and a needle protector. The needle protector comprises a sleeve (112) which is arranged on and in abutting contact

with the holder for the product container or the product container (Figures 1A-1D) such that the sleeve is shifts in a longitudinal axis with respect to the holder for the product container or the product container and surrounds the injection needle in an advanced position (Figure 1D). The holder for the product container together with the sleeve are inserted into the casing prior to the delivery of an injection and removed from the casing after the injection delivery to enable replacement of the product container as Bergens et al disclose that the housing parts are separable to allow for insertion and replacement of containers (line 44 of column 11 to line 57 of column 12). As seen in Figure 1A, the needle cap (127) accommodates the needle (123). The needle cap is considered to be guided by the sleeve onto the injection needle as the position of the sleeve (112) as seen in Figure 1A is seen to be capable of guiding the needle cap onto the injection needle. The needle cap is removed to enable exposure of the injection needle (lines 63-64 of column 11). The needle cap together with the injection needle are removed or capable of being removed from the casing after delivery of the injection to enable replacement of the needle cap and injection needle with an unused needle cap and injection needle.

6. Claims 17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacklich (U.S. Patent No. 4,444,560). Jacklich discloses an injection device has a casing (9) and operating means pivotable in a radial direction about a fulcrum (51) which is arranged laterally on the injection device. The operating means includes a one-piece lever with an integral lever arm and protrusion (65) projecting from the lever arm at a fixed angle substantially perpendicular to the lever arm towards a longitudinal axis

of the injection device. The protrusion is co-operative with dispensing means (61) via a surface oblique relative to a longitudinal axis of the device. Pivoting of the operating means allows the dispensing means to be moved in an axial direction. The device also includes a releasing element (57) for releasing a dosage amount where the releasing element projects radially outward from inside the casing through an opening in the casing. As seen in Figures 1-3, at least a portion of the releasing element is inside the casing and the majority of the releasing element projects radially outward from inside the casing. The dimensions of the opening limit movement of the releasing element and the dosage amount is released by moving the releasing element from a first stopper on a first side of the opening to a second stopper on a second side of the opening opposite the first side (Figures 2 and 3). The first side of the opening is above 65 in Figure 2 and the second side of the opening is shown at 49 in Figure 2. The releasing element is considered to be capable of being moved from a first stopper which is part of one of the ratchet teeth below 65 to a second stopper which is part of one the ratchet teeth below 57. These ratchet teeth are considered to be on a first side of the opening and on a second side of the opening, respectively. As to claim 19, the sleeve (21) is considered to be capable of surrounding the injection needle and being shiftable.

### *Claim Rejections - 35 USC § 103*

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jacklich in view of Cosmai (U.S. Patent No. 4,850,967). Jacklich discloses the device substantially as claimed. Even though Jacklich discloses administering the fluid product in doses and providing an indicator for indicating a product amount, Jacklich is silent on the injector comprising a scale up to a total number of dosages amounts present and counts down by one unit on the scale when the dispensing means or operating means is operated. Cosmai discloses an injection device having an indicator which comprises a scale (i.e. the markings) and counts down by a dosage unit when the dispensing means are operated. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the indicator of Jacklich with a scale as taught by Cosmai as both Jacklich and Cosmai disclose devices for administrating a fluid in doses and Cosmai teaches that it is well known to provide a scale so that the number of dose being administered may be monitored.

***Response to Arguments***

9. Applicant's arguments with respect to claims 1-5, 6, 9, 12, 17, and 19 have been considered but are moot in view of the new ground(s) of rejection.

As to Applicant's arguments in lines 12-18 of page 8 and in lines 10-14 of page 11, the movement of the protrusion into contact with the ratchet teeth of the piston rod does allow for the displacement of the piston rod as the protrusion prevents return motion of the piston rod which is caused to move by the ratchet (57) (lines 28-44 of

column 2).

In response to Applicant's argument in lines 14-24 of page 9 that the device of Brunel does not have a repeated dispensability capability, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The device of Brunel is capable of releasing a predetermined amount of a dosage where the dosage amount is the entire amount of the fluid product in the container.

10. Applicant's arguments, see lines 13-26 of page 10, filed February 15, 2010, with respect to the rejection(s) of claim(s) 13 under 35 U.S.C, 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Bergens et al as detailed above.

***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bhisma Mehta/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767